

**REMARKS/ARGUMENTS**

Claims 50-86 are pending in the present application. Claims 65-68 stand withdrawn. Claims 50-64 and 69-86 stand rejected for the reasons stated in the Office Action. In response, claims 54 and 72 have been canceled, and claims 50, 53, 58, 62-64, 71, 76 and 85 have been amended. Support for these amendments can be found at page 5, lines 12-16; page 6, lines 5-8; page 18, lines 10-11 et seq.; page 22, lines 2-3; 13-15, among other places. No new matter is added by these amendments. Entry of these amendments is requested.

**With Respect to the Rejections Under 35 U.S.C. §112, Second Paragraph, Page 4 of the Office Action:**

Claims 50-54 stand rejected under 35 U.S.C. §112, second paragraph, for the reasons indicated on page 4 of the Office Action, as being indefinite for the use of “first” in claim 50 and because claim 54 does not appear to further limit claim 53 on which claim 54 depends. The Applicant believes that the use of “first” before “immunogenic antigen from a causal factor of a first mammalian disease” in claim 50 is necessary because claim 55, which depends on claim 50, further limits claim 50 by referring to “second immunogenic antigen from a causal factor of a second mammalian disease.” In view of this dependency, the Applicant respectfully requests reconsideration of this rejection.

Additionally, claim 53 has been amended to include the limitation of claim 54 and claim 54 has been canceled. Further, corresponding limitations are present in claims 71 and 72, therefore, claim 71 has been amended to include the limitation of claim 72 and claim 72 has been canceled. Withdrawal of these rejections is requested.

**With Respect to the Rejections Under 35 U.S.C. §112, First Paragraph, Pages 4-6 of the Office Action:**

Claims 50-64 and 69-86 stand rejected under 35 U.S.C. §112, first paragraph for the reasons indicated on pages 4-6 of the Office Action. First, the Applicant notes that claims 51, 52, 69, 70, 78, 79, 81 and 82 should not have been included in this rejection according to the Office Action on the paragraph bridging pages 4-5. Next, claims 50, 63 and 64 have been

amended to add “infectious” before “mammalian disease” and corresponding limitations in claims 58, 62, 76 and 85 have been deleted. Support for these amendments can be found in the specification as originally filed at page 5, lines 12-16; page 6, lines 5-8; page 18, lines 10-11 et seq.; page 22, lines 2-3; 13-15, among many other places. Claim 54 has been canceled for reasons not having to do with these rejections. The remaining claims 51-53, 55-62 and 71, 73-77, 80 and 83-85 depend on claims 50, 63 and 64. Therefore, withdrawal of these rejections is requested.

**With Respect to the Rejections of Claims 50 and 63 Under 35 U.S.C. §102(b), Page 6 of the Office Action:**

Claims 50 and 63 stand rejected under 35 U.S.C. §102(b) as being anticipated by Arakawa *et al.* for the reasons indicated on page 6 of the Office Action. For reasons not having to do with this rejection, claims 50 and 63 have been amended to add “infectious” before “mammalian disease” and corresponding limitations in claims 58, 62 and 76 have been deleted. Arakawa *et al.* does not appear to disclose such a limitation. Therefore, withdrawal of these rejections is requested.

**With Respect to the Rejections of Claims 50-62, 64 and 69-86 Under 35 U.S.C. §103, Pages 7-11 of the Office Action:**

Claims 50-62, 64 and 69-86 stand rejected under 35 U.S.C. §103 as being unpatentable over Arakawa *et al.* in combination with Gonzalez *et al.* (claims 50, 51 and 58); Arakawa *et al.* in combination with Manson *et al.* (claims 50 and 52); Arakawa *et al.* in combination with Gonzalez *et al.* and Hajishengallis *et al.* (claims 50, 51, 53-62); and Arakawa *et al.* in combination with Manson *et al.* and Gonzalez *et al.* (claims 50, 52, 64 and 69-86) for the reasons indicated on pages 7-11 of the Office Action. Claims 54 and 72 have been canceled for reasons not having to do with these rejections. Independent claims 50 and 64 have been amended for reasons not having to do with these rejections.

Arakawa *et al.* discloses compositions and methods for preventing autoimmune diabetes. The adjuvant/carrier (CTB) disclosed in Arakawa *et al.* is fused to an auto-antigen

(creating CTB-INS), that when used in animal immunization experiments results in stimulation of a Th2 and Th3 lymphocyte mediated immunotolerization response to the fusion antigens INS, when inoculated into non-obese diabetic mice, a specific animal model of a Th1 mediated autoimmune disease (Type 1 diabetes). This response resulted in the ACTIVATION of Th2 and Th3 lymphocytes that mediate IMMUNOSUPPRESSION of the inflammatory responses generated by cytotoxic lymphocytes preventing onset of the autoimmune disease. This type of immune response, IMMUNOSUPPRESSION, is useless for prevention of infectious diseases. By contrast, the fusion of CTB with infectious antigens, such as taught in the present application, results in STIMULATION of a strong humoral antibody response as well as STIMULATION of a thymic (Th1) cell response which generally activates a cellular (cytotoxic T cell) response to kill animal cells infected with the pathogenic organism.

No one of ordinary skill in the art, reading the disclosure in Arakawa *et al.* would have any reason to suspect that a CTB fusion protein could be used to generate an immune response against an infectious disease based on the Arakawa *et al.* disclosure. In fact, one of ordinary skill in the art would be led to the exact opposite conclusion, as discussed above. Therefore, there is no motivation to combine Arakawa *et al.* with the other references, and Arakawa *et al.* specifically teaches away from the present invention. Hence, Arakawa *et al.* in combination with any of the other references fails to establish a *prima facie* case of obviousness against claims 50 and 64, as presently amended. Claims 51-53, 55-62 depend on claim 50. Claims 81-85 depend on claim 64.

Claims 69-71, 73-80 and 86 depend on claim 63. For the reasons indicated above, claim 63 is believed to be patentable. Therefore, these rejections are believed to be moot with respect to claims 69-71, 73-80 and 86.

Therefore, withdrawal of these rejections with respect to claims 50-62, 64 and 69-86 is requested.

**With Respect to the Withdrawal from Consideration of Claims 65-68:**

As discussed below, the Applicant believes that claims 50, 59, 63 and 64 are now in condition for allowance and, therefore, claims 65-68 should be rejoined as a method of using a

patentable agent. If, however, the Patent and Trademark Office determines that claims 65-68 should not be maintained in this application for any reason, the Applicant authorizes the Patent and Trademark Office to cancel claims 65-68.

### CONCLUSION

For the reason stated above, the Applicant respectfully believes that all pending claims, claims 50-53, 55-71 and 73-86, are believed to be in condition for allowance and a Notice of Allowance is earnestly solicited. If, however, there remain any issues that can be resolved by telephone with the Applicants representative, the Examiner is encouraged to contact the undersigned directly.

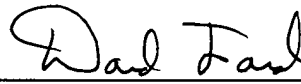
The Commissioner is hereby authorized to charge payment of any fees associated with this communication, including fees to extend the time to response to the outstanding Office Action, to Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK PC

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By



David A. Farah, M.D.

Reg. No. 38,134

Sheldon & Mak PC  
A Professional Corporation  
225 South Lake Avenue, Suite 900  
Pasadena, California 91101  
Tel.: (626) 796-4000  
Fax: (626) 795-6321

**Customer No.: 23676**